Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2001 list were published in the Federal Register in September 2001.

New Approvals

NADA Number: 141-179

Trade Name:	Avatec® plus BMD®
Ingredients:	Lasalocid sodium, bacitracin methylene disalicylate
Sponsor:	Alpharma, Inc.
Approval Date:	July 11, 2001
Status:	Over-the-counter
Route:	Oral
Species:	Growing turkeys
Drug Form:	Type A Medicated Articles to make two-way combination Type C medicated feeds.
Concentration:	Lasalocid sodium – 90.7 grams lasalocid activity per pound of Type A Medicated Article Bacitracin methylene disalicylate – 10, 25, 30, 40, 50, 60, or 75 grams bacitracin activity per pound of Type A Medicated Article
Indications:	For the prevention of coccidiosis caused by *Eimeria meleagrimitis*, *E. gallopavonis*, and *E. adenoeides*, and for increased rate of weight gain and improved feed efficiency.
Tolerance:	21CFR 556.347 Lasalocid: A tolerance is established for residues of 0.4 part per million for parent lasalocid in turkey liver, the target tissue. An acceptable daily intake (ADI) of 0.01 milligram per kilogram of body weight per day for lasalocid is established. 21CFR 556.70 Bacitracin: Tolerances for residues of bacitracin in uncooked edible tissues and eggs of turkeys are established at 0.5 part per million. The acceptable daily intake for total residues of bacitracin is 0.05 milligram per kilogram of body weight per day.
Withdrawal:	Zero days

21CFR 558.311 & 558.76

Supplemental Approvals

NADA Number: 141-099

This supplemental application provides for treatment and control of infections of additional life stages and species of gastrointestinal roundworms for topical use of 0.5% moxidectin solution on cattle.

Trade Name:	Cydectin® Pour-On
Ingredients:	Moxidectin
Sponsor:	Fort Dodge Animal Health
Approval Date:	June 18, 2001
Status:	Over-the-counter
Route:	Topical
Species:	Beef and dairy cattle
Drug Form:	Solution
Concentration:	0.5%
Indications:	For the treatment and control of internal and external parasites: **Gastrointestinal Roundworms:** *Haemonchus placei* – Fourth-stage larvae *Trichostrongylus colubriformis* - Fourth-stage larvae *Cooperia oncophora* - Fourth-stage larvae ***Cooperia pectinata*** - Adult *Cooperia punctata* - Fourth-stage larvae ***Cooperia spatulata*** - Adult ***Cooperia surnabada*** - Adult and fourth-stage larvae *Oesophagostomum radiatum* - Fourth-stage larvae *Nematodirus helvetianus* - Fourth-stage larvae

	Also to control infections and protect from reinfection with *Haemonchus placei* for 14 days after treatment, and *Oesophagostomum radiatum* for 28 days after treatment.
Tolerance:	21CFR 556.426 Moxidectin: Tolerances of 200 parts per billion (ppb) for parent moxidectin (marker residue) in liver (target tissue) and 50 ppb in muscle. A tolerance of 40 ppb is established for parent moxidectin in milk. The ADI has been established at 0.004 milligrams of moxidectin per kilogram of body weight per day.
Withdrawal:	Zero days
Patent No:	4,916,154 Expiration Date: April 10, 2007
Exclusivity:	3 years

21CFR 524.1451

NADA Number: 141-151

This supplemental application provides for the addition of cats for treatment of bacterial infections susceptible to marbofloxacin.

Trade Name:	Zeniquin®
Ingredients:	Marbofloxacin
Sponsor:	Pfizer, Inc.
Approval Date:	August 1, 2001
Status:	Prescription only
Route:	Oral
Species:	Dogs, cats
Drug Form:	Tablet
Concentration:	25 mg per tablet
Indications:	For the treatment of infections associated with bacteria susceptible to marbofloxacin.
Exclusivity:	3 years

21CFR 520.1310

NADA Number: 096-298

This supplemental application provides for an increased daily dosage in pasture cattle.

Trade Name:	Bovatec® Type A Medicated Article
Ingredients:	Lasalocid sodium
Sponsor:	Alpharma, Inc.
Approval Date:	July 25, 2001
Status:	Over-the-counter
Route:	Oral
Species:	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers)
Drug Form:	Type A Medicated Article to make Type C medicated feeds.
Concentration:	Type A Medicated Article (dry) containing 68 or 150 grams lasalocid activity per pound or Type A Medicated Article (liquid) containing 90.7 grams lasalocid activity per pound.
Indications:	For increased rate of weight gain.
Tolerance:	21CFR 556.347 Lasalocid: An acceptable daily intake (ADI) of 0.01 milligram per kilogram of body weight per day for lasalocid is established. Cattle: A tolerance is established for residues of 0.7 part per million for parent lasalocid in liver (target tissue).
Withdrawal:	Zero days

21CFR 558.311

Change of Sponsor Name and Address

From: Baxter Pharmaceutical Products, Inc.
110 Allen Rd.
Liberty Corner, NJ 07398

To: Baxter Healthcare Corp.
95 Spring St.
New Providence, NJ 07974
Drug labeler code: 010019

Change of Sponsor

The following NADAs and ANADAs were transferred from **Roche Vitamins, Inc. to Alpharma, Inc.**

033-950 035-688 035-805 036-361 040-209 041-647 041-648 041-649 041-650 041-651
041-652 041-653 041-654 041-984 046-920 048-486 048-761 049-287 055-040 092-507
095-546 096-298 096-933 097-085 100-901 102-485 105-758 107-996 112-661 112-687
114-794 121-553 123-154 125-933 126-052 128-686 131-894 132-447 134-185 134-284
135-321 135-746 136-484 137-536 137-537 139-075 139-190 139-235 140-579 140-581
140-859 140-865 140-867 141-025 141-109 141-150 200-140 200-167 200-242

One Executive Drive,
P. O. Box 1399,
Fort Lee, NJ 07024
Drug labeler code: 046573

The following NADAs and ANADAs were transferred from **Hoechst Roussel Vet. to Intervet, Inc.**

034-478 034-621 044-759 045-188 095-543 095-547 095-548 095-549 098-340 098-341
101-628 101-629 102-380 104-494 111-278 120-648 121-473 128-620 130-185 130-661
130-951 131-310 131-675 132-872 137-483 137-600 138-612 139-189 139-473 140-339
140-340 140-533 140-584 140-824 140-843 140-845 140-897 140-918 140-919 140-954
140-992 141-034 141-129 200-075 200-080 200-081 200-082 200-083 200-086 200-089
200-090 200-091 200-092 200-093 200-094 200-095 200-096 200-097 200-143

P.O. Box 318
405 State Street
Millsboro, DE 19966
Drug labeler code: 057926

The following NADAs and ANADAs were transferred from **Pfizer, Inc. to Phibro Animal Health, Inc.**

032-704 035-287 038-281 041-061 043-290 046-668 091-467 091-513 092-286 092-287
092-444 092-955 098-431 099-006 101-666 110-047 116-044 120-724 122-481 122-608
122-822 138-828 138-953 140-448 140-940 140-998 141-058 141-065 141-066 141-114

One Parker Plaza
Fort Lee, NJ 07024
Drug labeler code: 066104

NADA **039-583** was transferred from **Dow B. Hickam, Inc., Pharmaceuticals to Bertek Pharmaceuticals, Inc.**

12720 Dairy Ashford
Sugar Land, TX 77478
Drug labeler code: 062794

Suitability Petition Actions

Number:	01P-0382/CP1
Sponsor:	ECO LLC
Petition:	Request permission to file an ANADA for a generic new animal drug ivermectin/pyrantel which differs from the pioneer product, Heartgard® Plus, Merial Ltd., NADA 140-971 by the following characteristics: The generic product will consist of a different dosage form (compressed chewable tablet) from the pioneer.
Action:	Filed on September 4, 2001.
Number:	01P-0385/CP1
Sponsor:	Cross Vetpharm Group Ltd.
Petition:	Request permission to file an ANADA for a generic new animal drug oxytetracycline which differs from the pioneer product, Medamycin® Injectable, Boehringer Ingelheim Vetmedica, Inc., NADA 108-963, by the following characteristics: The generic product will consist of a different concentration (300 mg/ml) from the pioneer.
Action:	Filed on September 4, 2001.
Number:	01P-0394/CP1
Sponsor:	ECO LLC
Petition:	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Heartgard 30® Chewables, Merial Ltd., NADA 140-886 by the following characteristics: The generic product will consist of a different dosage form (compressed chewable tablet) from the pioneer.
Action:	Filed on September 6, 2001.
Number:	01P-0349/WDL1
Sponsor:	Smart Drug Systems, Inc.
Petition:	Request permission to withdraw petition to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Ivomec®, Merial Ltd., NADA 128-409 by the following characteristics: The generic product will consist of a different dosage form (compressed rod) and strength (35-60%) from the pioneer.
Action:	Filed September 17, 2001.
Number:	01P-0427/CP1
Sponsor:	Karen A. Sisson
Petition:	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan®, Merial Ltd., NADA 134-314 by the following characteristics: The generic product will consist of a different dosage form (liquid) from the pioneer.
Action:	Filed on September 20, 2001.
Number:	01P-0425/CP1
Sponsor:	First Priority, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Heartgard 30® Chewables, Merial Limited's NADA 140-886 by the following characteristic: The generic product will consist of a different dosage form (compressed chewable tablet) from the pioneer.
Action:	Filed on September 20, 2001.

Technical Amendment

The Final rule published in the Federal Register of October 27, 1998 (63 FR 57245 at 57246) inadvertently removed the tolerance for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline in milk. The Food and Drug Administration is amending Sec. 556.500 of the animal drug regulations to reflect the correct tolerance for the sum of residues of the tetracyclines in milk previously established of 0.3 part per million in milk.